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EXAMINER
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ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/040,373	BRAZHNIK ET AL.
	Examiner	Art Unit	
	David Silver	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on _09 January 2002_.

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) _1-28_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) _1-28_ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on _09 January 2002_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All   b) ☐ Some * c) ☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _4-21-04, 12-17-02,_.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1.   The information disclosure statements (IDS) submitted on June 13 2005,

May 15 2002, December 17 2002, Feb 14 2002, April 21 2004 are in compliance

with the provisions of 37 CFR 1.97. Accordingly, the information disclosure

statements are being considered by the examiner.

Claim Rejections - 35 USC § 101

2.   35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or
> composition of matter, or any new and useful improvement thereof, may obtain a patent
> therefor, subject to the conditions and requirements of this title.

a.   Claims 10-23 are rejected under 35 U.S.C. 101 because the

claimed invention is directed to non-statutory subject matter.

b.   Specifically, claims 10-23 are not technologically embodied since

the claims have not recited any limitations relating to a practical

application in the technological arts and have merely claimed non-

statutory subject matter (software). The examiner therefore submits that

the application has not recited any limitations that provide a tangible result

and have merely claimed software.

c.   Specifically, claims 10-23 recite "computer executable software

code" comprising of code, which is non-statutory subject matter as being

intangible (software code). As such, the claims are not limited to statutory

subject matter and is therefore are non-statutory. The examiner

respectfully suggests that claim 10, 16, and 20 be further limited by having

a physical embodiment. The examiner respectfully suggests that claims

be further limited to **tangible** computer readable medium.

> Section 2106 [R-2] (Patentable Subject Matter – Computer-Related
>
> Inventions) of the MPEP recites the following: "Data structures not
>
> claimed as embodied in computer-readable media are descriptive
>
> material per se and are not statutory because they are not capable
>
> of causing functional change in the computer. See, e.g.,
>
> Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760."

d.   As such, the claim is not limited to statutory subject matter and is

therefore non-statutory.

The examiner therefore submits that Applicant's have not recited any

limitations that provide a tangible embodiment and have merely **claimed**

software, which is not tangibly embodied.

An invention which is eligible for patenting under 35 U.S.C 101 is in the

"useful arts" when it is a machine, manufacture, process or composition of

matter, which produces a concrete, **tangible**, and useful result.

> "Tangible" – Applying In re Warmerdam, 33 F.3d 1354, 31 USPQ2d 1754
>
> (Fed. Cir. 1994), the examiner will determine whether
>
> > i.   there is simply software which is not tangibly embodied in a
> >
> > matter so as to be executed;

The examiner respectfully submits, under current PTO practice,

that the claimed invention does not recite a tangible embodiment and is

merely drawn to non-statutory subject matter (software code).

Claim Rejections - 35 USC § 102

2.   The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3.   Claims 1-9, 20, 25-28 are rejected under 35 U.S.C. 102(e) as being

anticipated by Volker Tresp ("Tresp" hereinafter) (US Patent 6,272,480).

b.   As per claim 1, Tresp discloses a method for creating a computer

model of diabetes, comprising:

ii.   identifying data relating to diabetes, the data relating

changes in biological states to biological attributes of diabetes

(col.: 1 lines: 18-29, column: lines: 2 lines 23-28 "influence

variables");

iii.   identifying a plurality of biological processes related to the

data, the plurality of biological processes defining at least one

portion of the disease state of diabetes **(col.: 2 lines: 24-26, col.: 4**

lines: 33-41 "quantity of food" in the reference is directly

related to the quantity of protein, referring to disease state,

col. 4 lines 24-26: to warn a person a portion of the, or the

whole, simulation result is used in conjunction with reference

material to identify whether the said result is "showing" the

disease state); and

iv.   combining the plurality of biological processes to form a

simulation of glucose metabolism in the context of multiple

macronutrient metabolism **(col.: 2 lines: 10-22, col.: 4 lines: 33-41**

multiple macronutrient metabolism correlates to

"carbohydrates" within the reference).

c.   As per claim 2, Tresp discloses a method of claim 1, further

comprising:

v.   producing a simulated biological attribute associated with at

least one biological attribute of diabetes from the combined plurality

of biology processes based on the combined plurality of biology

processes **(col.: 2 lines: 10-22)**;

vi.   comparing the simulated biological attribute with a

corresponding biological attribute associated with a reference

pattern of diabetes **(col.: 6 lines: 49-52, "risk analysis"**

inherently involves reference data taken from taken in a

control environment from a diseased biological system, such

data is then analyzed and compared to new/simulated result to

assess the risks); and

identifying the computer model as a valid computer model of

diabetes if the simulated biological attribute is substantially

consistent with the biological attribute associated with a reference

pattern of diabetes **(col.: 1 lines: 45-50 The computer model**

would inherently be substantially consistent when using a

neural network and sufficient training data. As such it would

be a valid model given its consistency to the reference

pattern.)

d.   As per claim 3, Tresp discloses a method of claim 1, wherein the

combining the plurality of biological processes includes:

vii.   forming a first mathematical relation among biological

variables associated with a first biological process from the plurality

of biological processes **(col.: 3 equation 1);** and

viii.   forming a second mathematical relation among biological

variables associated with the first biological process and a second

biological process from the plurality of biological variables

associated with the plurality of biological processes **(col.: 3**

equation 2 Additionally, their associatively is shown in

equation 3).

e.   As per claim 4, Tresp discloses a method of claim 3, further

comprising:

ix.   creating a set of parametric changes in the first

mathematical relation and the second mathematical relation **(col.: 5**

lines: 44-49 training data, when introduced into the neural

network will serve as a parametric change in the mathematical

relations); and

x.   producing a simulated biological attribute based on at least

one parametric change from the set of parametric changes, the

simulated biological attribute being substantially consistent with at

least one biological attribute associated with a reference pattern of

diabetes **(col.: 5 lines: 59-61, col.: 6 lines: 32-36, col.: 1 lines:**

45-50 The computer model would inherently be substantially

consistent when using a neural network and sufficient training

data. As such it would be a valid model given its consistency

to the reference pattern.).

f.   As per claim 5, Tresp discloses a method of claim 3, further

comprising:

xi.   creating a set of parametric changes in the first

mathematical relation **(col.: 5 lines: 44-49 training data, when**

introduced into the neural network will serve as a parametric

change in the mathematical relations)

xii.   and a set of parametric changes in the second mathematical

relation, the set of parametric changes in the first mathematical

relation being associated with a first diabetes defect having its own

degree of severity **(col.: 5 lines: 59-61, col.: 6 lines: 32-36, col.: 1**

lines: 45-50 The computer model would inherently be

substantially consistent when using a neural network and

sufficient training data. As such it would be a valid model

given **its consistency to the reference pattern.),**

xiii.   the set of parametric changes in the second mathematical

relation being associated with a second diabetes defect having its

own degree of severity **(col.: 4 lines: 33-41, col.: 5 lines: 59-61)**.

The Examiner asserts that, according to column 5 lines 59-61, a

mathematical equation is used it is inherent that variables within the

formula contain magnitudes. Thus, it is inherent that the

magnitudes are actually severity. Hereinafter, the Examiner

asserts that Application's "severity" is in fact measurable within the

mathematical formula.   Therefor, it is inherently included in all

math-based simulators wherein the inputs have variable

magnitudes.

g.   As per claim 6, Tresp discloses a method of claim 3, further

comprising

xiv.   converting at least one biological variable from the group of

the first mathematical relation or second mathematical relation into

a biological variable that evolves over time **(col.: 1 lines: 51-61**

with emphasis on 55-57 "modeled in the form of a time

series"); and

xv.   producing a series of simulated biological attributes based

on the converted biological variable the series of simulated

biological attributes being substantially consistent with a

corresponding biological attribute associated with a reference

pattern of diabetes, the series of simulated biological attributes

representing the disease progression in the reference pattern of

diabetes (col.: 6 lines: 49-52, col.: 1 lines: 45-50 **The computer**

model would inherently be substantially consistent when

using a neural network and sufficient training data. As such it

would be a valid model given its consistency to the reference

pattern.).

h.   As per claim 7-9, the claims differ only in statutory basis to claims

1-3 (7-9 are the product for the method of claims 1-3).

i.   As per claim 20, Tresp discloses a computer executable software

code, comprising:

xvi.   code to define a plurality of biological processes related to a

disease state of diabetes including (col.: 2 lines: 38-41 **because**

the neural network is computerized it is inherent that code is

used in order to define the formulas associated with the

biological processes):

(1)   code to define a set of mathematical relations

associated with a first biological process from the plurality of

biological processes and associated with interactions among

biological variables associated with the first biological

process **(col.: 3 equation 1)**, and

(2)   code to define a set of mathematical relations

associated with a second biological process from the

plurality of biological processes and associated with

interactions among biological variables associated with the

second biological process **(col.: 3 equation 2)**,

xvii.   a first biological process from the plurality of biological

processes being associated with metabolism of at least two from

the group of carbohydrates, fats and proteins, a second biological

process from the plurality of biological processes being associated

with metabolism of glucose **(col.: 2 lines: 10-23, col.: 4 lines: 33-**

41).

j.   As per claim 25, Tresp discloses a method for creating a computer

model of diabetes, comprising:

xviii.   identifying data relating to diabetes, the data relating

changes in biological states to biological attributes of diabetes

(col.: 1 lines: 48-50 since the influencing variables are

measured they are also inherently identified);

xix.   identifying a plurality of biological processes related to the

data, the plurality of biological processes defining at least one

portion of the disease state of diabetes **(col.: 2 lines: 24-26, col.: 4**

lines: 33-41 "quantity of food" in the reference is directly

related to the quantity of protein, referring to disease state, col. 4 lines 24-26: to warn a person a portion of the, or the whole, simulation result is used in conjunction with reference material to identify whether the said result is "showing" the disease state); and

xx. combining the plurality of biological processes to form a simulation of at least one biological attribute of diabetes in the context of fat metabolism (col. 3 equation 3, col.: 2 lines: 10-23, col.: 4 lines: 33-41 Tresp's disclosure is broader than the limitations set forth by this claim. Hence, it covers biological attributes of diabetes in the context of fat metabolism.).

k. As per claim 26, Tresp discloses a method for creating a computer model of diabetes, comprising:

xxi. identifying data relating to diabetes, the data relating changes in biological states to biological attributes of diabetes (col.: 1 lines: 48-50 since the influencing variables are measured they are also inherently identified);

xxii. identifying a plurality of biological processes related to the data, the plurality of biological processes defining at least one portion of the disease state of diabetes (col.: 2 lines: 24-26, col.: 4 lines: 33-41 "quantity of food" in the reference is directly related to the quantity of protein, referring to disease state, col. 4 lines 24-26: to warn a person a portion of the, or the

whole, simulation result is used in conjunction with reference

material to identify whether the said result is "showing" the

disease state); and

xxiii.   combining the plurality of biological processes to form a

simulation of at least one biological attribute of diabetes in the

context of protein metabolism **(col. 3 equation 3, col.: 2 lines: 10-**

23, col.: 4 lines: 33-41 Tresp's disclosure is broader than the

limitations set forth by this claim. Hence, it covers biological

attributes of diabetes in the context of protein metabolism.).

I.   As per claim 27, Tresp discloses a computer model of a disease

state of diabetes, comprising:

xxiv.   a computer-readable memory storing **(col.: 2 lines: 38-41**

See Examiner assertion below):

    (3)   instructions defining a set of biological processes

    related to the disease state of diabetes **(col.: 2 lines: 38-41**

    See Examiner assertion below),

    (4)   at least two biological processes from the set of

    biological processes being associated with a set of

    mathematical relationships related to interactions among

    biological variables associated with the biological processes

    (col. 3, equations 1-3, col.: 4 lines: 33-41 it is inherent

    that the biological processes described by equations 1-3

    are associated the said equations. As such, the reverse,

in this case, also holds true. Since equation 3 is the combination of equation 1 and 2, there is an interaction and a relationship formed between the said two equations.),

(5)   the instructions defining a simulation of at least one biological attribute of diabetes in the context of fat metabolism **(col. 3 equation 3, col.: 2 lines: 10-23, col.: 4 lines: 33-41 Tresp's disclosure is broader than the limitations set forth by this claim. Hence, it covers biological attributes of diabetes in the context of fat metabolism.)**; and

(6)   a processor coupled to the computer-readable memory, the processor configured to execute the instructions **(col.: 2 lines: 38-41 See Examiner assertion below)**.

Examiner assertion: Tresp is describing a neural network operating on a computer ("computerized neural network"). A computer inherently has a *processor* to *execute instructions* and for instructions to be executed. It is inherent that the instructions are first stored in *memory* in order to be executed.

m.   As per claim 28, Tresp discloses a computer model of a disease state of diabetes, comprising:

xxv.   a computer-readable memory storing **(col.: 2 lines: 38-41**

See Examiner assertion above):

(1)   instructions defining a set of biological processes

related to the disease state of diabetes **(col.: 2 lines: 38-41**

See Examiner assertion above),

(2)   at least two biological processes from the set of

biological processes being associated with a set of

mathematical relationships related to interactions among

biological variables associated with the biological processes

(col. 3, equations 1-3, col.: 4 lines: 33-41 it is inherent

that the biological processes described by equations 1-3

are associated the said equations. As such, the reverse,

in this case, also holds true. Since equation 3 is the

combination of equation 1 and 2, there is an interaction

and a relationship formed between the said two

equations.),

(3)   the instructions defining a simulation of at least one

biological attribute of diabetes in the context of protein

metabolism **(col. 3 equation 3, col.: 2 lines: 10-23, col.: 4**

lines: 33-41 Tresp's disclosure is broader than the

limitations set forth by this claim. Hence, it covers

biological attributes of diabetes in the context of protein

metabolism.).; and

(4)   a processor coupled to the computer-readable

memory, the processor configured to execute the

instructions **(col.: 2 lines: 38-41 See Examiner assertion**

below).

Examiner assertion: Tresp is describing a neural network

operating on a computer ("computerized neural network"). A

computer inherently has a *processor* to *execute instructions*

and for instructions to be executed.   It is inherent that the

instructions are first stored in *memory* in order to be executed.

4.   Claims 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by

Stephen Brown ("Brown" hereinafter) (US Patent 5,956,501).

b.   As per claim 10, Brown discloses a computer executable software

code, comprising:

ii.   code to define a normal biological state through a set of

biological processes, each biological process from the set of

biological processes having its own associated parameter set, the

set of biological processes being related to glucose metabolism in

the context of multiple macronutrient metabolism **(col.: 6 line: 5**

$X(t_j)$ **refers to biological state at time** t_j; **wherein, $R(t_j)$ and $R(t_i)$**

is the set of biological processes and each process has its

own associated parameter 't', col. 1 lines 15-20 with emphasis

on line 16);

iii.   code to provide a plurality of predefined defect indicators,

each predefined defect indicator from the plurality of predefined

defect indicators being uniquely associated with a defect from a

plurality of defects associated with a disease state of diabetes,

each defect from the plurality of defects being associated with at

least one biological process from the set of biological processes

(col.: 4 top table.   Predefined defect indicators are shown in

column 2 of the table); and

iv.   code to receive a user-specified identification of a first defect

indicator from the plurality of predefined defect indicators, a first

defect from the plurality of defects being associated with the first

defect indicator, the parameter set associated with each biological

processes that is associated with the first defect being changed

based on the user-specified identification **(col. 2 lines 57-59, col. 4**

lines 58-61 input device for entering data, col.: 4 lines: 17-19

the self-care parameters would be entered by the user. Each

defect ("self-care parameter") is associated with an input

value, "parameter set" with each biological process (column 7,

lines 60-62 "metabolism rate")).

c.   As per claim 11, Brown discloses a computer executable software

code of claim 10, further comprising:

v.   code to determine at least one simulated biological attribute

based on the modified biological process associated with the first

defect, the simulated biological attribute being substantially

consistent with at least one corresponding biological attribute

associated with diabetes in a reference pattern of diabetes **(col.: 8**

line: 38).

Examiner asserts that it is inherent that Brown's disclosed

computer system performing the simulation has code to do

the above reference limitations, as mentioned by Brown in

abstract 4th line from the bottom.

d.   As per claim 12, Brown discloses a computer executable software

code of claim 10, further comprising:

vi.   code to receive a user-specified identification of a second

defect indicator from the plurality of predefined defect indicators, a

second defect from the plurality of defects being associated with

the second defect indicator, the parameter set associated with each

biological processes that is associated with the second defect being

changed based on the user-specified identification **(col. 2 lines 57-**

59, col. 2 lines 57-59, col.: 4 lines: 17-19 the self-care

parameters would be entered by the user. Each defect ("self-

care parameter") is associated with an input value, "parameter

set" with each biological process (column 7, lines 60-62

"hepatic and peripheral insulin sensitivities")).

Examiner asserts that it is inherent that Brown's disclosed

computer system performing the simulation has code to do

the above reference limitations, as mentioned by Brown in abstract 4th line from the bottom.

e.   As per claim 13, Brown discloses a computer executable software code of claim 12, wherein:

vii.   the first defect has an associated severity based on the change to the at least one associated parameter set **(col.: 7 line 66 to col.8 line 1 K_m refers to the associated severity);** and

viii.   the second defect has an associated severity based on the change to the at least one associated parameter set, the severity associated with the first defect being different from the severity associated with the second defect **(col.: 8 lines: 1-6 "K_1" and "K_3").**

f.   As per claim 14, Brown discloses a computer executable software code of claim 12, wherein:

ix.   the first defect has an associated severity based on the change to the at least one associated parameter set **(col.: 7 line 66 to col.8 line 1);** and

x.   the second defect has an associated severity based on the change to the at least one associated parameter set, the severity associated with the first defect being substantially similar to the severity associated with the second defect **(col.: 8 lines: 1-6 "K_1" and "K_3").**

The examiner asserts that a something "similar" is inherently non-

identical to something else, as given by the definition of the word

similar:

> similar: Related in appearance or nature; alike though **not identical.** .
>
> (Source: http://www.answers.com/similar&r=67)

Therefore, the examiner finds that claim 14 is a duplicate of claim

13.

g.   As per claim 15, Brown discloses a computer executable software

code of claim 10, further comprising:

> xi.   code to produce a simulated biological attribute based on the
>
> parameter set associated with each biological processes that is
>
> associated with the first defect **(col.: 2 lines: 32-34),**
>
> the simulated biological attribute being substantially consistent with
>
> biological attributes of a reference pattern of diabetes **(col.: 2 lines:**
>
> **10-13, col.: 7 lines: 22-30 The simulation would inherently be**
>
> **substantially consistent when using Brown's disclosed**
>
> **method and apparatus with sufficient input data. As such it**
>
> **would be a valid model given its consistency to the reference**
>
> **pattern.).**

2.   Claims 16-19, and 24 are rejected under 35 U.S.C. 102(e) as being

anticipated by David Rivonelli, "Rivonelli" hereinafter, (U.S. Patent 6,246,975).

h.   As per claim 16, Rivonelli discloses a computer executable

software code, comprising:

code

(1)   to provide a plurality of predefined defect indicators,

each predefined defect indicator from the plurality of

predefined defect indicators being uniquely associated with a

defect from a plurality of defects associated with a disease

state, each defect from the plurality of defects being

associated with at least one biological process from a set of

biological processes **(col.: 16 lines: 17-18, col.: 23 lines:**

30-36 When the generation method is performed, it

provides a description of all of the findings (defects)),

(2)   the set of biological processes being related to

glucose metabolism in the context of multiple macronutrient

metabolism **(col.: 12 lines: 63-67)**

code

(1)   to receive a user-specified identification of a first

defect indicator from the plurality of predefined defect

indicators, a first defect from the plurality of defects being

associated with the first defect indicator, the first defect

being associated with at least one biological process and its

associated parameter set, the at least one parameter set

associated with the first defect being changed based on the

user-specified identification; **(col.: 12 lines: 50-52, col.: 8 lines: 22-26 "user-specified" because the information is collected then transferred into computer readable format, col.: 16 lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein the second defect may be "cardiovascular disease")**, and

code

(1)   to receive a user-specified identification of a second defect indicator from the plurality of predefined defect indicators, a second defect from the plurality of defects being associated with the second defect indicator, the second defect being associated with at least one biological process and its associated parameter set, the at least one parameter set associated with the second defect being changed based on the user-specified identification **(col.: 12 lines: 50-52, col.: 8 lines: 22-26 "user-specified" because the information is collected then transferred into computer readable format, col.: 16 lines: 17-18 findings correlate to defects, col. 15 lines 64-67 wherein the second defect may be "disease of glucose intolerance")**.

The Examiner asserts that a change in one biological processes of an individual will very least be associated with another biological process for the fact that it is in the same

individual. As such their associatively will be generated by being "part" of one entity.

i.   As per claim 17, Rivonelli discloses a computer executable software code of claim 16, wherein:

      xii.   the first defect having an associated severity based on the change to the at least one associated parameter set **(col.: 12 lines: 12-21)**,

      xiii.   the second defect having an associated severity based on the change to the at least one associated parameter set, the severity associated with the first defect being different from the severity associated with the second defect **(col.: 12 lines: 12-21, col.: 13 lines: 51-53)**.

j.   As per claim 18, Rivonelli discloses a computer executable software code of claim 16, further comprising:

      xiv.   code to define a normal biological state through the set of biological processes, each biological process from the set of biological processes being associated with its own parameter set **(col.: 22 lines: 60-65)**.

k.   As per claim 19, Rivonelli discloses a computer executable software code of claim 16, wherein

      xv.   the plurality of defects are associated with type 2 diabetes **(col.: 6 lines: 58-62)**.

n.   As per claim 24, Rivonelli discloses a method for creating a

computer model of diabetes, comprising:

xxvi.   receiving a plurality of user-selected indications to define a

plurality of biological processes, each biological process from the

plurality of biological processes being based on data that relates to

changes in biological states to biological attributes of diabetes

(col.: 12 lines: 50-52, col.: 8 lines: 22-26 "user-specified"

because the information is collected then transferred into

computer readable format, col.: 16 lines: 17-18 findings

correlate to defects, col. 15 lines 64-67 wherein the second

defect may be "cardiovascular disease");

xxvii.   producing a representation of the plurality of biological

processes based on the user-selected indications, the plurality of

biological processes defining at least one portion of the disease

state of diabetes **(Abstract lines 1-4, The Examiner asserts that**

"reproducing a representation ... based on the user-selected

indications" means simulating the system based on user

inputs;

xxviii. produci ng a simulated biological attribute associated with at

least one biological attribute of diabetes based on the combined

plurality of biology processes **(col.: 13 lines: 51-53, Abstract lines**

1-4); and

I.   assessing a validity of the computer model based on a comparison

between the simulated biological attribute and a corresponding biological

attribute associated with a reference pattern of diabetes **(Abstract 1-4**

"simulating" The computer model would inherently be substantially

consistent because it uses predetermined criteria as well as user-

input as input into the simulation program. Additionally, the

Examiner asserts that the assessment can be performed by the

examinee and as such references column 12, lines 50-52 with

emphasis on the examinee's conclusion about the simulation.).

Claim Rejections - 35 USC § 103

3.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for

all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described
> as set forth in section 102 of this title, if the differences between the subject matter sought to
> be patented and the prior art are such that the subject matter as a whole would have been
> obvious at the time the invention was made to a person having ordinary skill in the art to which
> said subject matter pertains. Patentability shall not be negatived by the manner in which the
> invention was made.

4.   This application currently names joint inventors. In considering

patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that

the subject matter of the various claims was commonly owned at the time any

inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35

U.S.C. 103(a).

5.   Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Volker Tresp ("Tresp" hereinafter) (US Patent 6,272,480) as applied to claim

20 above, and further in view of David Rivonelli, Rivonelli hereinafter, (U.S.

Patent 6,246,975).

> m.   As per claim 21, Tresp substantially discloses the computer
>
> executable software code of claim 20, including code to define a set of
>
> parametric changes for a biological process **(Tresp, col.: 5 lines: 44-49**
>
> **training data, when introduced into the neural network will serve as a**
>
> **parametric change in the mathematical relations).** Tresp does not
>
> specifically disclose the code to receive user-specified identification of a
>
> first defect indicator.
>
> However, Rivonelli discloses an analogous system that includes steps to
>
> receive a user-specified input of a defect indicator **(Rivonelli, col.: 8**
>
> **lines: 22-26 "user-specified" because the information is collected**
>
> **then transferred into computer readable format, col.: 16 lines: 17-18**
>
> **findings correlate to defects, col. 15 lines 64-67 wherein the a defect**
>
> **may be "cardiovascular disease").** It would have been obvious to one
>
> of ordinary skill in the art of disease modeling, at the time of the present
>
> invention, to combine the teachings of the cited references. In fact,
>
> motivation combine would have been to allow the examinee to have a

much simple interface through the set of predefined findings (defect

indicators) in order to lessen the amount of work needed to be performed

by the examinee or physician.

n.   As per claim 22, Rivonelli discloses a computer executable

software code of claim 21, further comprising:

     i.   code to receive a user-specified identification of a second

defect indicator from the plurality of predefined defect indicators,

the second defect indicator from the plurality of defect indicators

being uniquely associated with a second defect from the plurality of

defects that is associated with the disease state of diabetes, the

second defect being associated with at least one biological process

and its associated parameter set, the at least one parameter set

associated with the second defect being changed based on the

user-specified identification **(col.: 12 lines: 50-52, col.: 8 lines: 22-**

26 "user-specified" because the information is collected then

transferred into computer readable format, col.: 16 lines: 17-18

findings correlate to defects, col. 15 lines 64-67 wherein the

second defect may be "disease of glucose intolerance").

     ii.   the first defect having an associated severity based on the

change to the at least one associated parameter set, the second

defect having an associated severity based on the change to the at

least one associated parameter set, the severity associated with

the first defect being different from the severity associated with the

second defect **(col.: 12 lines: 12-21, col.: 13 lines: 51-53)**.

2.   Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Volker Tresp ("Tresp" hereinafter) (US Patent 6,272,480) as applied to claim 20

above, and further in view of AIDA Case Selector and AIDA Explanations (See

IDS for reference information).

b.   As per claim 23, Tresp does not specifically discuss the limitations

of the claim. However, AIDA implemented an analogous system having

iii.   code to receive a user selection of a link representation from

a set of predefined link representations, each predefined link

representation in the set of predefined link representations being

associated with a different mathematical relationship, the user-

selected link representation being associated with the

interrelationship between a first biological variable and a second

biological variable **(AIDA Case Selector, page: 3 reference 1,**

page 4 reference 2),

iv.   a first link representation from the set of predefined link

representations being a representation of the first biological

variable having an effect on the second biological variable **(AIDA**

Explanations, page 3, Section "Blood glucose level (BGL)"),

v.   a second link representation from the set of predefined link

representations being a representation of instances of the first

biological variable being converted to instances of the second

biological variable **(AIDA Explanations, page 1, Section "Blood**

glucose units").

Conclusion

3.   The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure.

Reference U and V discuss modeling of diabetes through the use of

computers and input parameters and therefore apply to claims 1-28.

4.   Claims 1-28 are rejected.

Any inquiry concerning this communication or earlier communications from

the examiner should be directed to David Silver whose telephone number is

(571) 272-8634. The examiner can normally be reached on Monday thru Friday,

8am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Jean Homere can be reached on (571)272-3780. The fax

phone number for the organization where this application or proceeding is

assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Silver
Examiner
Art Unit 2128